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10/009,876	05/06/2002	Richard Gerardus F. Visser	92750/65	5153

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EXAMINER

KALLIS, RUSSELL

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 05/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/009,876

Applicant(s)

VISSER ET AL.

Examiner

Russell Kallis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 39-58 is/are pending in the application.
- 4a) Of the above claim(s) 51-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-50 and 54-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 December 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6/02.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I, Claims 39-50 and 54-58 drawn to a polynucleotide encoding a starch binding domain and a GBSSI from potato in the reply filed on 2/16/2005 is acknowledged. The traversal is on the ground(s) that the claims have been amended to a bacterial starch domain and the prior art teaches a starch domain from a fungal source. This is not found persuasive because the prior art reference teaches that a protein fusion containing a starch binding domain is known in the art.

The requirement is still deemed proper and is therefore made FINAL.

Claims 39-58 are pending. Claims 51-53 are withdraw. Claims 39-50 and 54-58 are examined.

### ***Specification***

The disclosure is objected to because of the following informalities: page 36 line 29 and page 37 line 25; competition and compared are misspelled. Appropriate correction is required.

### ***Claim Objections***

Claim 40 is objected to because of the following informalities: Claim 40 recites non-elected subject matter. Applicant must delete non-elected subject matter from the claims.

Appropriate correction is required.

Claim 54 is objected to because of the following informalities: Claim 54 is dependent from non-elected Claim 51. Appropriate correction is required.

Claim 55 is objected to because of the following informalities: Claim 55 is dependent from Claim 64 which has not yet been filed. Appropriate correction is required.

### ***Sequence Rules***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth: Figure 1 shows amino acid sequence but does not use sequence identifiers in the figure or in the description of the figure on page 31 of the specification. Further, Page 39 of the specification shows the amino acid sequence for a linker polypeptide but does not use a sequence identifier.

§ 1.821 Nucleotide and/or amino acid sequence disclosures in patent applications;

(d) Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

Applicant must amend the claims, specification, and/or drawings to insert sequence identifiers.

### ***Drawings***

The drawings are objected to because the drawings are poor copies of the originals and are not legible enough for printing. For Example the figure legend of figure 2 is blurred. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31-50 and 54-58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a starch branching enzyme genetic construct and methods of expressing and altering the affinity for starch in plants transformed therewith does not reasonably provide enablement for GBSSI genetic constructs and methods of expressing and altering the affinity for starch in plants transformed therewith. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are broadly drawn to a genetic construct comprising a nucleotide sequence encoding a fusion protein comprising a bacterial starch binding domain and an enzyme that interacts with starch, plants transformed therewith, a method of expressing the enzyme that

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interacts with starch in a plant and a method of increasing the affinity for starch by expressing a fusion protein that interacts with starch in a plant.

Applicants teach how to make constructs comprising a nucleotide sequence encoding a bacterial starch binding domain and a fusion protein that interacts with starch and altered (Example IV-V, pages 38-40) and increased starch branching in potato transformed with a heterologous branching enzyme (Example III and III-1, page 37).

Applicants do not teach plants transformed with a genetic construct comprising a nucleotide sequence encoding a fusion protein comprising a bacterial starch binding domain (SBD) linked to a GBSSI protein that interacts with starch, and methods of expressing a GBSSI in a plant or a method of increasing the affinity for starch of a GBSSI protein linked to a bacterial starch domain or how to make and/or use plants transformed therewith or thereby.

The state-of-the-art is such that one of skill in the art cannot predict the starch phenotype of a plant comprising extra copies of a GBSSI encoding polynucleotide and over-expressing GBSSI in starch granules. An all too common outcome of attempting to increase a particular biochemical or physiological property of a plant is that the desired phenotype was not observed even though the plants were transformed and the protein was expressed. Mutant amylase free potato plants, complemented/transformed and expressing a potato GBSSI encoding polynucleotide showed increased GBSSI activity but showed no detectable differences in their starch suggesting other factors may be controlling or regulating the interaction or affinity between GBSSI and starch (Flipse E. *et al.* Theoretical and Applied Genetics, 1994, Vol. 88 pp. 369-375; see abstract and Table 1 page 371). Further evidence of this complex interaction was shown in the amylose free potato mutant complemented/transformed with a cassava GBSSI

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encoding polynucleotide had levels of GBSSI activity equal to or higher than the GBSSI activity of a wild type plant yet only recovered 60% of the amylose content of the wild type (Shah N. *et al.* Plant Cell and Environment, 1999, Vol. 22; pp. 1311-1318; see abstract and page 1315).

Given the lack of guidance in the instant specification, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through a multitude of non-exemplified plants transformed with a genetic construct comprising a polynucleotide encoding a GBSSI enzyme and a bacterial starch binding domain for increases in starch GBSSI affinity to determine how to use the genetic construct comprising a polynucleotide encoding the bacterial starch domain and the GBSSI enzyme and plants transformed therewith.

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled throughout the broad scope of the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 56-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 56 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: an expression step and a statement wherein the fusion protein is expressed.

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Claim 58 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a transformation step and a statement wherein the affinity of the enzyme has been increased.

The term "affinity" in claim 58 is a relative term which renders the claim indefinite. The term "affinity" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear whether affinity refers to an increase in the presence of the enzyme or an actual increase in the ability to bind starch.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 58 recites the broad recitation "starch and/or starch granules", and the claim also recites "starch or starch granules" which is the narrower statement of the range/limitation.



***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 45, 50 and 55 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed inventions encompass untransformed plants and seeds, which are a product of nature and not one of the five classes of patentable subject matter. Claims 45, 50 and 55 are drawn to parts such as seeds and progeny of the transformed plant. Due to Mendelian inheritance of genes, a single gene introduced into a parent plant would only be transferred at most to half the male gametes and half the female gametes. This translates into only three fourths of the progeny having at least a single copy of the transgene and one quarter of the progeny without a copy of the transgene. Since the claim encompasses progeny that lack the transgene, the claim encompasses plants and seeds that are indistinguishable from plants and seeds that would occur in nature. See *American Wood v. Fiber Distintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 39, 41 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Dalmia B. *et al.* Biotechnology and Bioengineering, 1995; Vol. 47 pp. 575-584 in light of GenBank Accession gi: 142654; April 26, 1993.

The claims are broadly drawn to a genetic construct comprising a nucleotide sequence encoding a fusion protein comprising a bacterial starch binding domain and an enzyme that interacts with starch, plants transformed therewith, a method of expressing the enzyme that interacts with starch in a plant and a method of increasing the affinity for starch by expressing a fusion protein that interacts with starch in a plant.

Dalmia teaches a genetic construct comprising a bacterial starch domain, a nucleotide sequence encoding a protein that interacts with starch and a linker between the enzyme and the starch binding domain (see entire page 576); wherein starch binding domains #3 and #6 of *B. circulans* in Figure 1 of the application are the same as those of *B. macerans* shown in GenBank Accession gi: 142654, and thus the reference teaches all the limitations of Claims 39, 41 and 44.

Claims 39, 42-50, 54-57 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Kortstee A. *et al.* The Plant Journal, 1996; Vol. 10, No. 1; pp. 83-90.

Kortstee teaches transformation of potato with a chimeric construct encoding a fusion protein comprising the transit peptide (i.e. signal sequence) and first two amino acids of GBSSI protein from potato fused to a starch branching enzyme from *E. coli* that comprises a bacterial starch binding domain; wherein the transformed plants produced starch and starch granules having correctly processed recombinant starch branching protein and starch having an increased branching degree (see Summary and Experimental Procedures); and thus the reference teaches all the limitations of Claims 39, 42-50, 56-57 and 58.

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All claims are rejected.

Claim 40 is deemed free of the prior art given the failure of the prior art to teach or reasonably suggest a genetic construct comprising a polynucleotide encoding a fusion protein comprising a potato GBSSI enzyme linked to a starch binding domain of a cyclodextrin glycosyltransferase(CGTase) from *Bacillus circulans*.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Kallis Ph.D.  
May 4, 2005

  
**RUSSELL P. KALLIS, PH.D.**  
**PATENT EXAMINER**